REMARKS

Claims 1-3 are currently pending in the application with claims 1 and 3 amended above.

Independent claim 1 is directed to a method for minimizing scarring and/or preventing excessive scar formation at an injury site. The method comprises applying to the injury site a first aid bandaging material that has been coated with a defibrinogenating agent, such as ancrod, in a therapeutically effective amount to minimize scarring at the application site. It is clear from the specification that fibrinogen and fibrin play key roles in scar formation and that a reduction in fibrin deposition at the wound site can minimize scarring. Reduction is achieved by administration of a defibrinogenating agent such as ancrod, which cleaves fibrinopeptide A from fibrinogen to produce a non-cross-linked fibrin. The claimed method, therefore, requires administration of a defibrinogenating agent to achieve *fibrin reduction* to prevent scarring at the wound site.

Rejection Under 35 U.S.C. §112, second paragraph

Claims 1-3 are rejected under 35 U.S.C. §112, second paragraph as being indefinite According to the Office Action, the claims are rendered vague and indefinite for the inconsistency of the preamble and recitation of the process steps. Claim 1 is amended above to reconcile the purpose of the method as recited in the preamble with the process steps.

Withdrawal of the rejection under 35 U.S.C. §112, second paragraph is respectfully requested.

Rejection Under 35 U.S.C. §103

Claims 1-3 are rejected under 35 U.S.C. §103(a) as being unpatentable over newly cited Petti et al. in view of Edwardson et al. and Chen et al. According to the Office Action, newly cited reference, Petti et al. teach a method for preventing scarring comprising administration of a defibrinogenating agent.

Disqualification of Petti Reference Under 35 U.S.C. §103(c)(1)

The following is a quotation of 35 U.S.C. §103(c)(1):

> "Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person."

Effective November 29, 1999, subject matter which was prior art under former 35 U.S.C. 103 via 35 U.S.C. 102(e) was disqualified as prior art against the claimed invention if that subject matter and the claimed invention "were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person." (MPEP 706.02(k)).

Applicant's undersigned representative states that the present application and U.S. publication 2003/0219431 cited in the office action were, at the time the invention of the present application was made, commonly owned by the inventor, Samn Raffaniello (Petti) and subject to an obligation of assignment to Empire Pharmaceuticals, Inc., the predecessor in interest to the present assignee, Neurobiological Technologies, Inc. Thus, Petti et al., is ineligible as prior art against the present claims.

Edwardson et al.

Citing the abstract, col.26, lines 25-35 and col. 6, lines 35-61, the Office Action states that "Edwardson et al. teach applying directly to bandages, sutures, or other solid support, therapeutic anticoagulant agents, such as ancrod in combination with fibrin materials." Applicants do not agree.

The claimed method includes two elements: 1) the administration of a defibrinogenating agent to a wound site 2) to minimize scarring. Neither element is taught by the cited references.

The Office Action suggests that because of the "comprising" language of claim 1, Applicant's method could include administration of fibrin. In the present case, however, the preamble of the claim should be viewed as a necessary element of the claims. Applicant's specification makes clear that fibrin and fibrinogen play a role in scar formation and that the inventor was working on the particular problem of minimizing scarring by reducing fibrin deposition at the wound site. In light of the specification, therefore, to read the claim indiscriminately to potentially include administration of a defibrinogenating agent plus fibrin is in conflict with reality. By virtue of its preamble, the invention so described is restricted to a method in which fibrin deposition at the wound site is reduced, which is not true with respect to all scenarios recited in just the body of the claim. Thus, Applicant respectfully submits that the claim preamble in this instance does not merely state a purpose or intended use for the claimed method; rather, those words do give 'life and meaning' and provide further positive limitations to the invention claimed.

Edwardson et al. neither teaches nor suggests 1) administration of a defibrinogenating agent to reduce fibrin deposition or 2) a method to minimize scarring. Edwardson et al. does teach methods for making a fibrin monomer composition and using it in conjunction with a solid support (bandage material) as a fibrin sealant (see abstract).

Edwardson et al. further teaches that fibrin monomer or noncrosslinked fibrin can be obtained from any source *so long as* the fibrin monomer can be converted to fibrin polymer or the noncrosslinked fibrin can be converted to crosslinked fibrin. According to Edwardson et al., fibrin from a whole blood source will retain sufficient quantities of prothrombin, factor XIII and other components of the coagulant cascade so that the noncrosslinked fibrin I can be converted to crosslinked fibrin II without the addition of exogenous thrombin and factor XIII. (col. 5, lines 9-24.)

Edwardson et al. further teaches that noncrosslinked fibrin I, which is obtained from exposure of fibrinogen to ancrod, is preferred because it can more readily, as compared to fibrinogen, be converted to crosslinked fibrin. According to Edwardson, if the noncrosslinked fibrin I comes in contact with blood, for example, on a wound, the patient's own thrombin and factor XIII may convert the fibrin I to crosslinked fibrin II. A method for generating fibrin monomer from a fibrinogen source using ancrod as the thrombin-like enzyme is disclosed at column 6, lines 25-35 of Edwardson et al.

Beginning at col. 8, line 53, Edwardson provides a lengthy discussion of employing thrombin-like enzyme that is immobilized on a solid support. The support-bound enzyme can be readily removed from the plasma, thereby preventing the composition comprising noncrosslinked fibrin from being contaminated with enzyme.

Taken together, the teachings of Edwardson et al. suggest to the skilled artisan that Edwardson et al. did not intend for there to be ancrod present in the final fibrin preparation.

Unlike Edwardson et al., it is clear from the specification that Applicant's claimed method does not envision the application of either fibrin or fibrinogen to a wound; rather Applicant's method seeks to minimize scarring by reducing fibrin deposition at the wound site.

The objective of Edwardson et al., therefore, is to enhance clotting by applying a concentrated amount of fibrin monomer to a wound site where it subsequently becomes crosslinked to form a stable clot. In contrast, the object of the present invention is to achieve a decreased fibrin deposition at the wound site in order to reduce scarring. Addition of exogenous fibrinThe two methods could not be more different.

In support of this position, Applicant submits the Declaration of Gregory del Zoppo, M.D. whose expertise is in the field of hematology.

Chen et al.

Chen et al. relates to drug delivery and in particular a drug delivery composition that enhances solubility of therapeutic agents, which may include defibrinogenating agents; the drug delivery composition forms a clear aqueous dispersion upon mixing with an aqueous medium, making it possible to apply a "coating" to a bandage material. There is, however, no teaching or suggestion in Chen et al. that administration of a defibrinogenating agent to an injury is desirable for any reason let alone that a defibrinogenating agent such as ancrod is efficacious for minimizing scarring at an injury site. In the absence of such a teaching, Chen et al. does not disclose the present invention or render it obvious. In the absence of a teaching that ancrod reduces scarring at a wound site, there is no apparent reason why one of skill in the art would modify the teachings of Edwardson et al. by substituting a coating

material of Chen et al. containing ancrod, particularly where, as here, substitution, or even addition of a defibrinogenating agent with a concentrated fibrin composition capable of clot formation would obtain an opposite result, i.e., reduced clotting.

Withdrawal of the rejection under 35 U.S.C. §103(a) is respectfully requested.

It is believed that the application is in condition for allowance, and such action is respectfully requested. If a telephone conference would be of assistance in advancing the prosecution of the subject application, the Examiner is invited to telephone applicant's undersigned attorney at the number provided below.

Respectfully submitted,

Kathy Smith Dias
Attorney for Applicant(s)
Reg. No. 41,707

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HESLIN ROTHENBERG FARLEY & MESITI P.C.
5 Columbia Circle
Albany, New York 12203
Telephone: (518) 452-5600
Facsimile: (518) 452-5579